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National
Voluntary
Laboratory
Accreditation
Program

Bulk Asbestos Analysis

Eric B. Steel
Jennifer Verkouteren
David F. Alderman

NIST HANDBOOK 150-3

U.S. Department of Commerce
Technology Administration
National Institute of Standards
and Technology

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[2] Some elements at Boulder, CO 80303.

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August 1994

U.S. Department of Commerce
Ronald H. Brown, Secretary

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Mary L. Good, Under Secretary for Technology

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Arati Prabhakar, Director

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PREFACE

NIST Handbook 150-3 presents the technical requirements of the National Voluntary Laboratory Accreditation Program (NVLAP) for accreditation under Bulk Asbestos Analysis. It is intended for information and use by staff of accredited laboratories, those laboratories seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the accreditation requirements.

This publication supplements NIST Handbook 150, "NVLAP Procedures and General Requirements," which contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR) plus all general NVLAP procedures, criteria, and policies. The criteria in NIST Handbook 150 encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987). Handbook 150-3 contains information that is specific to the Bulk Asbestos Analysis program and does not duplicate information contained in the Procedures and General Requirements. It is organized to cross-reference with Handbook 150; for example, Section 285.3 of Handbook 150 presents the description and goal of NVLAP, whereas Section 285.3 of Handbook 150-3 presents a description of the Bulk Asbestos Analysis program. Where there is no material specific to the field of accreditation, the section number is omitted.

Any questions or comments on this handbook should be submitted to the National Institute of Standards and Technology/NVLAP, Building 411, Room A162, Gaithersburg, MD 20899; phone (301) 975-4016; FAX (301) 926-2884.

ACKNOWLEDGMENTS

The technical contents of this handbook were originally developed by the Surface and Microanalysis Science Division of the National Institute of Standards and Technology. The experience and knowledge gained since the inception of the Bulk Asbestos Analysis program dictated that we revise the handbook to reflect new requirements and information.

Special recognition is given to Thomas G. Laubenthal, a NVLAP technical expert who contributed significantly to the content, editing and formatting of this handbook. Appreciation is also expressed to Peter Cooke who provided most of the definitions used in this handbook. Additional recognition is due to the many laboratories and NVLAP technical experts who provided helpful comments and suggestions to improve the program. Also, thanks are extended to Vanda R. White, whose efforts helped bring this handbook to fruition.

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SUMMARY

Any laboratory (including commercial, manufacturer, university, or federal, state, or local government laboratory) that performs the test method that comprises the Bulk Asbestos Analysis Program may apply for NVLAP accreditation. Accreditation will be granted to a laboratory that satisfactorily fulfills the conditions for accreditation defined in the NVLAP Procedures: Title 15, Part 285 of the Code of Federal Regulations (see NIST Handbook 150). These conditions include satisfactory performance in selected proficiency testing as required, and fulfilling the on-site assessment requirements, including resolution of identified deficiencies. The names of NVLAP-accredited laboratories are published in the NVLAP annual directory and other media to which information is regularly provided.

Test method covered: The U.S. Environmental Protection Agency's "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Subpart F, Appendix A, or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building material.

Period of accreditation: One year, renewable annually.

On-site assessment: Visit by a technical expert to determine compliance with the NVLAP criteria before initial accreditation and every two years thereafter. Additional monitoring visits as required.

Assessors: Technical experts with experience in the appropriate field of testing.

Proficiency Testing: Each laboratory is required to test and analyze proficiency testing sample material(s) for specific test methods. Advance notice and instructions are given before testing is scheduled. The completed test data report is sent to NVLAP, or as directed to the proficiency test NVLAP contractor. A summary of results is sent to the participants.

Granting Accreditation: Based upon satisfactory on-site assessment and resolution of deficiencies, proficiency testing, and technical evaluation of applicable laboratory information.

Fees: Payments are required as listed on the fee schedule, including the administrative/technical support fee, on-site assessment fee, proficiency testing fee, and test method fee.

Sec. 285.1 Purpose

The purpose of this handbook is to set out procedures and technical requirements for accreditation by NVLAP of laboratories which perform the U.S. Environmental Protection Agency (EPA) "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in Title 40 of the Code of Federal Regulations (CFR), Part 763, Subpart F, Appendix A, or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building material. It complements and supplements the NVLAP programmatic procedures and general requirements found in NIST Handbook 150. The interpretive comments and additional requirements contained in this handbook make the general NVLAP criteria specifically applicable to the Bulk Asbestos Analysis Program. Specific circumstances under which departures from the NVLAP general procedures are allowable within the scope of the Bulk Asbestos Analysis Program are also addressed in this handbook.

Sec. 285.2 Organization of procedures

(a) The handbook is organized to cross-reference with NIST Handbook 150, *NVLAP Procedures and General Requirements*.

(b) In addition, the handbook contains three appendices:

(1) Appendix A provides examples of a Scope of Accreditation and a Certificate of Accreditation for the Bulk Asbestos Program;

(2) Appendix B provides the General Operations Checklist, which NVLAP assessors use during an on-site technical assessment to evaluate a laboratory's ability to conduct testing in general;

(3) Appendix C provides the Specific Operations Checklist, which NVLAP assessors use during an on-site technical assessment of a laboratory which analyzes bulk asbestos samples.

Sec. 285.3 Description and goal of NVLAP Bulk Asbestos Analysis Program

The purpose of the Bulk Asbestos Program is to accredit testing laboratories to assure that laboratories are competent to analyze bulk samples for asbestos using polarized light microscopy (PLM).

Public Law 99-519, "Asbestos Hazard Emergency Response Act of 1986, referred to as AHERA, requires that the National Institute of Standards and Technology (formerly the National Bureau of Standards) develop an accreditation program for laboratories conducting analyses of bulk samples of asbestos-containing material.

Sec. 285.4 References

References and sources for the Bulk Asbestos Program follow:

(a) NIST Handbook 150 (March 1994); available from:

NIST/NVLAP
Building 411, Room A162
Gaithersburg, MD 20899

Phone: (301) 975-4016
Fax: (301) 926-2884;

(b) U.S. Environmental Protection Agency "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Subpart F, Appendix A, or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building material;

(c) "Asbestos-Containing Materials in Schools; Final Rule and Notice," as found in 40 CFR, Part 763, Subpart E;

(d) U.S. Environmental Protection Agency "Method for the Determination of Asbestos in Bulk Building Materials" (EPA/600/R-93/116), July 1993, R. L. Perkins and B. W. Harvey; available from:

NTIS
U.S. Department of Commerce
Springfield, VA 22161

Phone: (800) 553-6847.

Refer to NTIS document # PB93-218576 or U.S. EPA document # EPA/600/R-93/116 (July 1993) when ordering.

Sec. 285.5 Definitions

Accuracy: The degree of agreement of a measured value with the true or expected value.

Asbestos: A commercial term applied to the asbestiform varieties of six different minerals. The asbestos types are chrysotile (asbestiform serpentine), amosite (asbestiform grunerite), crocidolite (asbestiform riebeckite), and asbestiform anthophyllite, asbestiform tremolite, and asbestiform actinolite. The properties of asbestos that caused it to be widely used commercially are: 1) its ability to be separated into long, thin, flexible fibers; 2) high tensile strength; 3) low thermal and electrical conductivity; 4) high mechanical and chemical durability, and 5) high heat resistance.

Becke Line: A band of light seen at the periphery of a specimen when the refractive indices of the specimen and the mounting medium are different; it is used to determine refractive index.

Bias: A systematic error characterized by a consistent (non-random) measurement error.

Binder: With reference to a bulk sample, a component added for cohesiveness (e.g., plaster, cement, glue, etc.).

Birefringence: The numerical difference between the maximum and minimum refractive indices of an anisotropic substance. Birefringence may be estimated, using a Michel-Levy chart, from the interference colors observed under crossed polarizers. Interference colors are also dependent on the orientation and thickness of the grain, and therefore are used qualitatively to determine placement in one of the four categories listed below.

Qualitative	*Quantitative(N-n)*
none	0.00 or isotropic
low	≤ 0.010
moderate	0.011-0.050
high	> 0.050

Bulk Sample: A sample of building material taken for identification and quantitation of asbestos. Bulk building materials may include a wide variety of friable and nonfriable materials.

Color: The color of a particle or fiber when observed in plane polarized light.

Compensator: A device with known, fixed or variable retardation and vibration direction used for determining the degree of retardation (hence the thickness or value of birefringence) in an anisotropic specimen. It is also used to determine the sign of elongation of elongated materials. The most common compensator is the first-order red plate (530-550nm retardation).

Control Chart: A graphical plot of test results with respect to time or sequence of measurement, together with limits within which they are expected to lie when the system is in a state of statistical control.

Detection Limit: The smallest concentration/amount of some component of interest that can be measured by a single measurement with a stated level of confidence.

Dispersion Staining (focal masking): An optical means of imparting apparent or virtual color to transparent substances by the use of stops in the objective back focal plane; it is used to determine refractive indices.

Error: The difference between the true and measured value of a quantity.

Extinction: The condition in which an anisotropic substance appears dark when observed between crossed polars. This occurs when the vibration directions in the specimen are parallel to the vibration directions in the polarizer and analyzer. Extinction may be complete or incomplete; common types include parallel, oblique, symmetrical and undulose.

Extinction Angle: For fibers, the angle between the extinction position and the position at which the fiber is parallel to the polarizer or analyzer privileged directions.

Fiber: With reference to asbestiform morphology, a structure consisting of one or more fibrils.

Friable: Refers to the cohesiveness of a bulk material, indicating that it may be crumbled or disaggregated by hand pressure.

Gravimetry: Any technique in which the concentration of a component is determined by weighing. As used in this document, it refers to measurement of asbestos-containing residues after sample treatment by ashing, dissolution, etc.

Homogeneous: Uniform in composition and distribution of all components of a material, such that multiple subsamples taken for analysis will contain the same components in approximately the same relative concentrations.

Matrix: Nonasbestos, nonbinder components of a bulk material. Includes such components as cellulose, fiberglass, mineral wool, mica, etc.

Michel-Levy Scale of Retardation colors: A chart plotting the relationship between birefringence, retardation and thickness of anisotropic substances. Any one of the three variables can be determined if the other two are known.

Morphology: The structure and shape of a particle. Characterization may be descriptive (platy, rod-like, acicular, etc.) or in terms of dimensions such as length and diameter (see asbestiform).

Pleochroism: The change in color or hue of colored anisotropic substance when rotated relative to the vibration direction of plane polarized light.

Point Counting: A technique used to determine the relative projected areas occupied by separate components in a microscope slide preparation of a sample. For asbestos analysis, this technique is used to determine the relative concentrations of asbestos minerals to nonasbestos sample components.

Precision: The repeatability of measurement data; the similarity of successive independent measurements of a single magnitude generated by repeated applications of a process under specified conditions.

Refractive Index (index of refraction): The ratio of the velocity of light in a vacuum relative to the velocity of light in a medium. It is expressed as *n* and varies with wavelength and temperature.

Sign of Elongation: Referring to the location of the high and low refractive indices in an elongated anisotropic substance, a specimen is described as positive when the higher refractive index is lengthwise (length slow), and as negative when the lower refractive index is lengthwise (length fast).

Standard Reference Material (SRM): A reference material certified and distributed by the National Institute of Standards and Technology.

Visual Estimation: An estimation of concentration of asbestos in a sample as compared to the other sample components.

Sec. 285.6 NVLAP documentation

Checklists contain definitive questions about all aspects of the NVLAP criteria for accreditation. NVLAP programs incorporate two types of checklists: (a) a General Operations Checklist and (b) a Specific Operations Checklist. In the former case, the questions are applicable to evaluating a laboratory's ability to conduct testing in general. They address factors such as the laboratory's organization, management, and quality system in addition to its testing competency. In the latter case, the checklist questions are specific to the test method(s) in the given program, and focus on the testing requirements including the assessor's observations of test demonstrations.

(a) The NVLAP General Operations Checklist is contained in Appendix B. The questions in the General Operations Checklist follow and are numbered to correspond to the requirements in NIST Handbook 150.

(b) The Specific Operations Checklist for the Bulk Asbestos Program is contained in Appendix C, along with a comment sheet used by the assessor in conjunction with this checklist. The comment sheet is primarily used to explain deficiencies noted on the checklist. Additionally, the assessor may use the sheet to make comments on aspects of the laboratory's performance other than deficiencies. A similar comment sheet is provided to the assessor for use with the General Operations Checklist.

Sec. 285.22 Assessing and evaluating a laboratory

(a) On-Site Assessment

(1) The NVLAP assessor may request manuals and/or documented procedures in advance of the on-site assessment to reduce time spent at the laboratory. The laboratory should be prepared for conducting test demonstrations, have equipment in good working order, and be ready for examination according to the requirements identified in this present handbook, NIST Handbook 150, and the laboratory's quality manual. The assessor will need time and work space to complete assessment documentation during the time at the laboratory.

(2) An assessor performs the following activities during a typical on-site assessment:

(i) Conducts an entry briefing with the laboratory manager to explain the purpose of the on-site visit and to discuss the schedule for the day(s). At the discretion of the laboratory manager, other staff may attend the briefing.

(ii) Reviews laboratory quality manual (if not previously requested and supplied) and records. At least one laboratory staff member must be available to answer questions; however, the assessor may wish to review the documents alone. The assessor does not usually ask to take any laboratory documents with him and documents previously supplied will be returned.

(iii) Physically examines equipment and facilities and observes the demonstration of selected procedures by appropriate personnel assigned to conduct the tests, and interviews the personnel. The demonstrations must include sample test material(s), establishment of test conditions, and the setup/use of major equipment. The assessor may provide the proficiency test sample and request a specific demonstration.

(iv) Completes an On-site Assessment Report which contains the minimum requirements prescribed in NIST Handbook 150, Sec. 285.22(b)(2), as well as copies of the completed checklists. At the exit briefing, the report is signed by the assessor and the laboratory's Authorized Representative to acknowledge the discussion but does not necessarily indicate agreement; challenge(s) may be made through NVLAP. All observations made by the NVLAP assessor are held in the strictest confidence.

(b) Proficiency Testing

(1) The proficiency testing program may be conducted by NVLAP or by a NVLAP-approved contract laboratory. The proficiency testing materials, in general, are representative examples of bulk insulation materials or their derivatives. The material will test the laboratory's ability to follow the method and to achieve the proper accuracy, precision, and detection limits.

(2) Each laboratory will be sent test samples, data sheets, and instructions for performing the test and reporting the results. The test shall be conducted in accordance with the specific test method using the laboratory's normal operating procedures. Proficiency testing shall not be contracted out to another laboratory. Any special NVLAP instructions shall also be followed. The special instructions are designed to ensure uniformity in procedures among participants. Completed data sheets shall be returned to NVLAP or its designated contractor for analysis by the date specified on the data sheets. Failure to return the proficiency testing data sheets by the deadline date will result in penalties which may include failing that round.

(3) Proficiency testing may involve materials or artifacts that must be returned to NVLAP for use by other participants. These materials shall be protected from damage both in the laboratory and during shipment back to NVLAP or its designated contractor. Examples of such materials and artifacts are: permanently mounted slides, photographs, glasses, and special optical materials. These materials may be used to determine testing performance for specific subparts of the test method. Unless otherwise noted, laboratories should keep proficiency testing materials for use as in-house instructional materials.

(4) All analysts (including those in sub-facilities) shall participate in proficiency testing. Each analyst shall separately analyze, record, and report test results. A single result is to be reported by the laboratory. The test results are to be used for interanalyst comparisons and entered into the quality system records.

(5) The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual laboratories will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during laboratory visits. Any problems indicated by proficiency testing will be discussed with appropriate laboratory personnel, who will then be responsible for developing and implementing

plans for resolving the problems. Accreditation decisions will be based on satisfactory resolution of proficiency testing deficiencies.

(6) If an accredited laboratory fails a round of proficiency testing, it must do the following in order maintain its accreditation:

(i) provide within 30 days of notification of failure detailed, written documentation to NVLAP, that includes an analysis of why the laboratory failed each part of the test, and what corrective actions it has taken (analyst training, revised procedures, quality assurance activities, etc.) to resolve its analytical problems so as to avoid similar errors in the future; documented evidence that the corrective actions have been effectively implemented is required; and

(ii) participate successfully in the next round of proficiency testing.

(7) If a laboratory has been NVLAP-accredited and fails any two rounds of proficiency testing within a set of three (3) consecutive rounds, **its accreditation will be immediately suspended**. In order to regain accreditation, the laboratory shall undergo a complete on-site assessment to determine the cause of the deficiencies, and to determine that effective corrective actions have been implemented. The laboratory shall provide NVLAP with documentation within 30 days of the assessment, which adequately demonstrates that the deficiencies noted by the assessor have been satisfactorily resolved. Failure to perform fully satisfactorily in the on-site assessment will result in accreditation remaining suspended.

(8) The full cost of any on-site assessment shall be paid in advance by the laboratory. NVLAP staff will make every effort to expedite these extraordinary assessments to give a laboratory every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

(9) Failure to participate in a round of proficiency testing will result in **immediate suspension of accreditation**, and the laboratory shall successfully participate in the next regularly scheduled round in order to have its accreditation reinstated.

(10) Occasionally laboratories may be sent blind samples to test their proficiency under normal conditions. The results of any blind testing will be used to determine a laboratory's continued compliance with NVLAP requirements.

Sec. 285.23 Granting and renewing accreditation

Laboratories granted NVLAP accreditation are provided with two documents: a Scope of Accreditation and a Certificate of Accreditation. Appendix A shows samples of these accreditation documents for the Bulk Asbestos Program.

Sec. 285.33 Criteria for accreditation

(b) Organization and management

The conditions for continued accreditation of a sub-facility in the Bulk Asbestos Program are contained in this section.

(1) As stated in Sec. 285.5 of NIST Handbook 150, *Definitions*: "NVLAP previously differentiated between *main facilities* and *sub-facilities*. This distinction is no longer recognized. (Exception: As long as there is no break in accreditation, any laboratory previously accredited as a sub-facility may request to be 'grandfathered' in its accreditation renewal under the former classification as a sub-facility, including the unique conditions associated with that classification.)"

(2) Main laboratory facilities and sub-facilities are defined as follows:

(i) A *main laboratory facility* permanently maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests for which it seeks accreditation; implements all quality assurance procedures; and maintains and retains all records, and issues test reports.

(ii) A *sub-facility* is physically separate from, but considered an extension of, the main facility. Although it may have all staff, equipment, procedures, and documentation necessary to perform the requisite tests, it receives technical direction and quality management from the main facility. A sub-facility shall maintain staff, equipment, procedures, documentation, and facilities necessary to

perform the tests for which it seeks accreditation.

(3) To operate as a sub-facility, a laboratory **shall be technically dependent** on the main facility; technical management and supervision shall be provided by the main facility. Quality assurance activities of the sub-facility shall be directed by the main facility. The nature, scope, and frequency of on-site quality assurance reviews by the main facility quality manager shall be clearly defined in the quality manual and be appropriate for the nature and scope of work performed by the sub-facility. Copies of all permanent quality assurance and personnel records shall be retained at the main facility. Quality assurance data from each sub-facility shall be frequently and routinely compared both to the main facility's data and data from other sub-facilities. Records of such comparisons shall be retained in quality assurance records along with actions taken to evaluate and resolve differences.

NVLAP accreditation of a laboratory main facility does not extend to accreditation of sub-facilities unless the sub-facilities have been evaluated separately. These facilities are uniquely identified in the NVLAP accreditation documents. A NVLAP-accredited laboratory shall not represent test data produced at any non-accredited sub-facility as having been produced by an accredited facility.

(4) NVLAP will renew the accreditation of a sub-facility (in addition to the main facility) if:

(i) the laboratory was accredited as a sub-facility prior to October 1, 1993;

(ii) the laboratory main facility meets all NVLAP accreditation criteria;

(iii) the laboratory main facility satisfactorily documents and maintains quality assurance procedures addressing the applicable sub-facility;

(iv) the sub-facility complies with all applicable NVLAP criteria; and

(v) the main facility is accredited for all test methods for which its sub-facilities are accredited.

(5) NVLAP requires that sub-facilities undergo on-site assessments and participate in proficiency testing.

(c) Quality system, audit and review

(1) The laboratory shall define quality objectives for ensuring accurate and precise analytical data. These objectives should be the benchmark by which the laboratory management assesses overall and individual performance.

(2) Under its quality system, the laboratory shall develop and implement procedures covering all the technical requirements of this handbook. The quality system's periodic reviews shall reflect adherence to NVLAP requirements and the laboratory's quality objectives. These reviews should also reflect positive aspects of the quality system as well as deficiencies.

A laboratory analyst should be able to obtain enough information from the laboratory's quality documentation to perform analyses in the absence of the laboratory manager. Specific evidence that all staff members have been trained for their role in the quality assurance program is required.

(3) The most recent editions of the documents listed in Sec. 285.4 *References* in this handbook shall be available as references in maintaining the quality system. There shall, also, be available in the laboratory a general reference text on optical mineralogy or crystallography and a general reference text on statistics and/or quality assurance.

(d) Personnel

(1) The laboratory shall maintain records on each staff member, including a résumé, assigned duties, laboratory procedures for which they are qualified, training, quality assurance activities, and proficiency testing information.

(2) All analysts and technical supervisors must understand polarized light microscopy and its application to crystalline materials. They should understand what measurements are possible with the polarized light microscope, how they are performed, and how to form conclusions about the identity of a component from the measurements. They should be able to measure

all optical properties required for the identification of regulated asbestos types, and in particular, the index of refraction by the immersion method. These measurements shall be satisfactorily performed upon request during an on-site visit by a NVLAP Technical Expert. Knowledge of several techniques of refractive index measurement (e.g., Becke line, dispersion staining and oblique illumination), in addition to other analytical methods (e.g., x-ray diffraction, transmission electron microscopy, and scanning electron microscopy) is also helpful.

(3) Analyst proficiency is the key to providing reliable data. All analysts shall be tested routinely to evaluate their performance. Test results shall be recorded in the personnel folder or equivalent of each staff member, and be available during NVLAP on-site assessments. Testing techniques may include, but not be limited to reanalysis of materials, intra- and interlaboratory comparison, analysis of standards, reference materials, NVLAP proficiency testing materials, and blind testing. Testing shall be frequent enough to ensure quality analyses. Test specimens should include asbestos-containing and look-alike materials routinely examined by the analysts, and those not often encountered. Problems shall be discussed with the analyst, and corrected according to documented procedures. Subsequent quality assurance tests shall determine whether the problem has been corrected. The laboratory shall ensure the quality of analyses while the problem is being corrected. All corrective actions shall be documented in monthly quality assurance summaries, periodic laboratory audits, and individual analyst's files.

(4) The laboratory shall be organized so that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work. The laboratory shall be able to demonstrate that the sample work load required for each analyst is consistent with accurate and precise analytical measurement.

(5) The laboratory shall have a detailed, documented description of its training program for new and current staff members. The analytical results obtained by new staff members shall be checked by an analyst whose performance has been demonstrated to be acceptable, or by using an independent technique, until the new staff member demonstrates the required level of performance. The laboratory shall establish and document performance criteria to determine when a new analyst is qualified to work independently. Reference documents, texts and current scientific and industry periodicals shall be made available to all analysts to keep their knowledge up to date. An ongoing process of practice, training and professional development is essential to the maintenance and improvement of analyst expertise.

(6) Employees shall be aware of the extent of their area of responsibility. This information should be available in the required job descriptions found in the quality documentation and individual files.

(e) Accommodation and environment

(1) The laboratory has the proper facilities, including space, lighting, environmental control, etc. to perform analyses and store asbestos adequately.

(2) The work space shall be monitored for asbestos contamination on a routine basis. Laboratory blanks, using asbestos-free materials, shall be prepared and analyzed with sufficient frequency to detect contamination of laboratory equipment or supplies including, but not restricted to, glass slides, cover slips, refractive index liquids, sampling instruments, analytical instruments (microscopes), workstations, and cleaning fluids. There shall be written procedures for dealing with any contamination. Records of these contamination control activities shall be maintained.

(f) Equipment and reference materials

(1) The laboratory shall be furnished with the equipment and facilities necessary for the correct performance of the tests and measurements for which it is accredited. The laboratory shall have proper facilities for storage of bulk asbestos to prevent contamination and to maintain sample integrity. Samples shall be stored so that sample identification is properly maintained and samples can be readily retrieved. Safe working conditions while handling bulk asbestos should be maintained.

(2) The list of required equipment and supplies follows.

(i) Polarized light microscope with the following characteristics:

- binocular or monocular; one of the oculars shall have a cross hair reticle or functional equivalent; one of the oculars must have a magnification of at least 8X;
- low ($\geq$5X and $\leq$15X), medium ($>$15X and $<$40X), and high ($\geq$40X) objectives, or similar magnifications;
- light source;
- 360-degree rotatable stage;
- substage condenser with iris diaphragm;
- polarizer and analyzer that can be placed at 90 degrees to one another;
- accessory slot for wave plates and compensators;
- wave retardation plate: approximately 550 nm retardation;

(ii) low-power binocular microscope or stereomicroscope, approximately 10-45X, with light source;

(iii) biohazard hood of Class I or better;

NOTE: A Class I Biohazard Hood or recirculating hood with a HEPA filter is required for the safe and non-contaminating handling of bulk asbestos materials in the laboratory. For the accreditation program, the purpose of the hood is to protect the laboratory environment from contamination with the potentially large quantities of asbestos handled during routine preparation and macroscopic examination of building materials. A Class I hood is a ventilated cabinet for personnel and environmental protection, with an inward airflow away from the operator. The cabinet exhaust air must be treated to protect the environment before it is discharged to the outside atmosphere or must exhaust HEPA-filtered air back into the laboratory. A minimum inward velocity of air into the hood opening of 75 fpm is recommended. [Reference: Standard Number 49, National Sanitation Foundation, Ann Arbor, MI, (313) 769-8010.]

(iv) sampling utensils (tweezers, razors, knives, forceps, probe needles, pliers, etc.);

(v) sample containers (glassine paper, glass plates, ceramic bowls, petri dishes, etc.);

(vi) microscope slides and cover slips;

(vii) refractive index liquids: 1.490-1.570, 1.590-1.720 in increments of less than or equal to 0.005;

(viii) NIST-traceable standards for the major asbestos types (SRM 1866 and 1867);

(ix) mortar and pestle;

(x) thermometer; and

(xii) calibrated refractive index solids or refractometer (or access to) for the calibration of refractive index liquids.

(3) A list of optional equipment and supplies follows:

(i) dispersion staining objective or functional equivalent;

(ii) high dispersion refractive index liquids;

(iii) blue "daylight" filter;

(iv) monochromatic ($\sim$589 nm) filter or functional equivalent;

(v) mechanical stage and/or point-counting stage;

(vi) mill and/or blender;

(vii) analytical balance (readability of 1 mg or better);

(viii) muffle furnace (temperature range to 500 °C or higher, stable to $\pm$10 °C or

better) including appropriate temperature calibration materials/equipment;

(ix) drying oven;

(x) hydrochloric acid; and

(xi) filtration supplies.

(4) It is recommended that periodic cleaning and maintenance be performed on all microscopes by qualified professional technicians.

(5) Routine maintenance of the polarized light microscope is performed, including alignment of the light source and substage assembly to provide proper illumination, centering objectives, focusing the cross hair reticle in the field of view, testing for coincidence between the cross hair reticle and the privileged direction of the polarizer, and determining whether the polarizer and analyzer are normal to one another.

(6) The refractive index liquids used for analysis shall be calibrated with an accuracy of ± 0.004.

(g) Measurement traceability and calibration

(1) The best way to ensure measurement accuracy and precision is by the use of standards, such as samples from past NVLAP proficiency testing rounds, past EPA Asbestos Bulk Sample Analysis Quality Assurance Program testing samples (quantitation of these was determined by consensus so reported quantities may not reflect actual amounts), or samples that have been well characterized by intra- and interlaboratory testing and alternate methods of analysis. Specific preparation techniques as found in Appendix C of the U.S. EPA "Method for the Determination of Asbestos in Bulk Building Materials" may be used for the preparation and characterization of samples to be used as standards.

Assistance for the calculation of accuracy, precision and required quantitation leading to the generation of control charts can be found in many analytical chemistry texts. A detailed reference list of publications and texts regarding these issues can be found in U.S. EPA "Method for the Determination of Asbestos in Bulk Building Materials."

(2) The precision and accuracy of the analyses shall be determined by the laboratory on the types of samples received for analysis. Precision describes the ability to repeat a measurement, and accuracy describes the correctness of a measurement. Precision can be determined routinely by comparing results of a single sample from multiple analysts and/or from multiple analyses by the same analyst. The precision in the quantitative analysis of a sample by a single analyst is typically defined by the variation observed among multiple slides prepared from the sample or through blind reanalysis of a particular sample. Accuracy should be determined using materials of known concentration, such as past proficiency testing materials, prepared standards (in-house or purchased), or materials analyzed by an independent technique. Appendix C of the U.S. EPA "Method for the Determination of Asbestos in Bulk Building Materials" describes how bulk asbestos samples can be prepared for use as training standards. Precision and accuracy must be determined for both qualitative and quantitative analyses. For qualitative analyses, the laboratory must determine whether multiple analyses of the same sample, either by the same or different analysts, and/or by different analytical techniques, yield the same results (asbestos present or not, and type of asbestos) and whether they are correct. For quantitative analyses, the laboratory shall determine an average value for the concentration of asbestos in the sample, with an associated measurement uncertainty. This uncertainty is determined from the precision and accuracy of several analyses conducted on known quality assurance standards. An analyst's precision and accuracy data shall be documented and reflected in the required monthly summaries.

The accuracy of the technique is dependent on the amount of asbestos in the sample and the characteristics of the matrix; this should be recognized by the laboratory and provisions for such, incorporated into the quality system. An example of the variability that can be expected with concentration is given in the U.S. EPA "Method for the Determination of Asbestos in Bulk Building Materials." Standards that are available for quantitative asbestos analysis, such as NVLAP proficiency testing materials or

typical manufactured standards, give the concentration of asbestos in units of weight percent; however, the PLM technique yields results in units of relative area. The conversion of weight percent to area percent requires knowledge of the density and relative grain size of the components of the sample—factors that are often not easily determined. However, the difference between weight percent and area percent is often obscured by the semi-quantitative nature of the PLM technique, and for many samples there is no significant difference between weight and area percent results. The exceptions to this statement occur when the sample contains components (such as organic materials) that have a very different density than the asbestos minerals or when there is a large disparity in relative grain size. It is recommended that laboratories use weight percent and point-counted standards when training an analyst for quantitation of asbestos by the PLM technique.

(3) There should be an error rate of less than 1% on the qualitative analysis for samples that contain chrysotile, amosite, and crocidolite. A slightly higher error rate may occur for samples that contain anthophyllite, actinolite, and tremolite, as it can be difficult to distinguish among the three types. The laboratory should monitor the error rates and use them as a guide to determine when an analyst requires additional training to ensure the integrity of measurements. Any types of samples that present particular problems shall be identified, and specific procedures shall be described for dealing with the samples to reduce the error rate to an acceptable level. This can include either rejection of the samples before or during analysis, or use of additional analytical or sample preparation techniques. Additional information and techniques are found in the U.S. EPA "Method for the Determination of Asbestos in Bulk Building Materials.

(4) Quantitative results should be represented in the form of tabulated numeric values for each analyst on the various materials. Control charts documenting precision, accuracy and error rates should be prepared to assist laboratory personnel in characterizing the overall laboratory and individual performance. These summaries should be filed appropriately and will undergo evaluation during NVLAP on-site visits. All procedures for such measurements shall be documented in the quality system documentation.

(5) When reporting the percentage of asbestos in a sample, the following considerations should be taken:

(i) The asbestos phase(s) must be positively identified by polarized light microscopy and the optical parameters recorded before stating that asbestos is present in any quantity, including trace.

(ii) The reported quantity of asbestos, including trace, should be consistent on the slide mounts used for quantitation. This assumes that the sample is reasonably homogeneous or has been homogenized to ensure that each subsample is representative of the composition of the total sample.

(iii) A point count or equivalent method is required for quantitation. If asbestos is counted during the point count, the percentage should be reported; if asbestos is consistently observed but not counted, trace should be reported; if no consistent quantity of asbestos is observed, zero concentration should be reported. Trace is considered to be a quantity of asbestos that is above the laboratory's detection limit and below their limit of quantitation.

The detection limit for asbestos is a function of the analyst's capabilities, the laboratory's reliable blank level, and the visibility of asbestos. The visibility of asbestos is a function of microscope image contrast and resolution, asbestos fiber size, sample matrix, slide preparation, etc. The level of quantitation may be defined as the concentration at which a statistical uncertainty may be determined for the quantity of asbestos reported. The uncertainty may be determined by analysis of standard materials and is a function of the same parameters listed for the limit of detection. If a method other than the point count is used for quantitation, the level of quantitation for the method must be determined and documented by the laboratory in order to report the presence of a trace of asbestos.

(h) Calibration and test methods

(1) The laboratory shall use the test method contained in The U.S. EPA "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" or the current U.S. EPA method for the analysis of asbestos in building material. The laboratory must have written procedures that describe how the method is implemented in the laboratory. The laboratory is responsible for ensuring that it implements the latest revision of the method. The laboratory shall conform in all respects with the test method except when a departure becomes necessary for technical reasons. The laboratory shall have data to demonstrate that departures from the test method do not detract from the expected precision or accuracy of the measurement. Laboratories utilizing departures from a test method shall have written procedures detailing how the analysis is conducted. These procedures shall include criteria to determine when such departures are warranted.

(2) To document the positive identification of asbestos in a sample, the analyst shall record the average optical properties for the population of each asbestos type, including morphology, color and pleochroism, indices of refraction (n_D), birefringence, extinction characteristics, sign of elongation, and any other distinguishing characteristics observed. For chrysotile and amosite, refractive indices shall be determined parallel and perpendicular to elongation (γ' and α') with an accuracy of ± 0.005. For anthophyllite, tremolite, and actinolite, γ and α shall be measured if the population of fibers display biaxial optics; otherwise the requirements for chrysotile and amosite apply. For crocidolite, the refractive indices should be determined parallel and perpendicular (α' and γ') to elongation with an accuracy of approximately ± 0.01.

(i) Handling of calibration and test items

Samples shall be held for at least 30 days unless client specifications or regulations prevent otherwise. It is recommended that clients be notified of the sample disposal policies of the laboratory. Because of the legal issues surrounding asbestos analysis, laboratories may consider keeping samples indefinitely or returning the samples to the client with a signed chain-of-custody form.

(j) Records

Records may be kept in hard copy or computer form (with an adequate back-up system), but they shall be readily accessible and secure. The period of retention shall be three years unless a longer period is required by the client, regulation, or the laboratory's own procedures. The records to be maintained include:

(1) sample custody records;

(2) original data collected, signed (or initialed), and dated by analyst;

(3) contamination monitoring data;

(4) calibration and verification data;

(5) data and results of quality control;

(6) equipment and maintenance records; and

(7) test reports.

(k) Certificates and reports

(1) In addition to the test report requirements found in Sec. 285.33(k) of NIST Handbook 150, the following information shall also be reported for each sample:

(i) presence or absence of asbestos and the identification of each asbestos type;

(ii) estimate of the average area percentage (or weight percentage), accompanied by an estimate of the error, for each type of asbestos present;

(iii) identity and area percentage of other fibrous and matrix materials, if known; and

(iv) color and macroscopic description (and any other information that serves to identify and describe the sample).

(2) Specific sampling procedures should be described where appropriate. This is especially important for samples containing multiple layers.

(3) A laboratory using analytical techniques in addition to PLM that yield results in terms of weight percent (e.g., gravimetry or x-ray diffraction) can report results in weight percent.

(4) A laboratory, which subcontracts its asbestos analysis work, must ensure that the subcontracted laboratory meets all the requirements of this handbook and Sec. 285.33(l) of NIST Handbook 150.

APPENDIX A

SAMPLE ACCREDITATION DOCUMENTS

United States Department of Commerce
National Institute of Standards and Technology

NVLAP®

ISO/IEC GUIDE 25:1990
ISO/IEC GUIDE 58:1993
ISO 9002:1994

Certificate of Accreditation

DEPARTMENT OF COMMERCE ★ UNITED STATES OF AMERICA ★

LABORATORY, INC.
ANYTOWN, MD

is recognized under the National Voluntary Laboratory Accreditation Program for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. Accreditation is awarded for specific services, listed on the Scope of Accreditation for:

BULK ASBESTOS FIBER ANALYSIS

January 1, 19xx
Effective until

For the National Institute of Standards and Technology

NVLAP LAB CODE: 0000

National Institute of Standards and Technology

NVLAP®

National Voluntary Laboratory Accreditation Program

ISO/IEC GUIDE 25:1990
ISO/IEC GUIDE 58:1993
ISO 9002:1994

Scope of Accreditation

BULK ASBESTOS FIBER ANALYSIS **NVLAP LAB CODE 0000**

Laboratory, Inc.
1 Main Street
Anytown, MD 00000
John Doe Phone: 301-555-1212

NVLAP Code	*Designation*
18/A01	40 Code of Federal Regulations Chapter I (1-1-87 edition) Part 763, Subpart F, Appendix A or the current U. S. Environmental Protection Agency method for the analysis of asbestos in building materials by polarized light microscopy.

January 1, 19xx

Effective until

For the National Institute of Standards and Technology

APPENDIX B

GENERAL OPERATIONS CHECKLIST

GENERAL OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses general accreditation criteria prescribed in applicable sections of NIST Handbook 150, *NVLAP Procedures and General Requirements*.

This checklist follows and is numbered to correspond to the *NVLAP Procedures and General Requirements*, Subsection 285.33. The numbers in square brackets identify related checklist items. A small black triangle appears in the left-hand margin of selected lines of text throughout this checklist; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP).

Place an "X" beside each checklist item which represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments in this list or on the attached comment sheets. Place a check beside all other items you observed or verified at the laboratory.

SEC. 285.33 CRITERIA FOR ACCREDITATION

(b) ***Organization and management***

(1) The laboratory shall be:

_____ (i) legally identifiable;

Legal name of laboratory ownership: _____

(ii) organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the NVLAP requirements [see also (b)(2)(i), (c)(2)(ii)];

_____ (iii) properly identified on the NVLAP Application.

(2) The laboratory shall:

_____ (i) have managerial staff with the authority and resources needed to discharge their duties [see also (b)(1)(ii), (c)(2)(ii)];

_____ (ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

_____ (iii) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

_____ (iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

_____ (v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

_____ (vi) have a technical manager (however named) who has overall responsibility for the technical operations;

Name of person: _____

_____ (vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

Name of person: _____

_____ (viii) nominate deputy(ies) in case of absence of the technical or quality manager;

Name(s): _____

_____ (ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights [see also (c)(2)(xviii)];

_____ (x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs [see also (c)(2)(xiv), (c)(6)(ii), (g)(3)];

_____ (xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

(c) ***Quality system, audit and review***

(1) The laboratory shall:

_____ (i) have an established and maintained quality system appropriate to the type, range and volume of calibration and testing activities it undertakes;

_____ (ii) have the elements of the quality system documented;

_____ (iii) ensure that the quality documentation is available for use by the laboratory personnel;

_____ (iv) define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services;

_____ (v) have the laboratory management which ensures that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned;

_____ (vi) ensure that the quality manual is maintained current under the responsibility of the quality manager [see also (c)(2)(iv)].

Date of quality manual: _____

Date of latest update: _____

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the NVLAP requirements. The quality manual and related quality documentation shall contain:

_____ (i) a quality policy statement, including objectives and commitments, by top management;

_____ (ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

_____ (iii) the relations between management, technical operations, support services and the quality system;

_____ (iv) procedures for control and maintenance of documentation [see also (c)(1)(vi), (j)(1)];

_____ (v) job descriptions of key staff and reference to the job descriptions of other staff;

_____ (vi) identification of the laboratory's approved signatories (list here or in the comments section): _____

_____

_____ (vii) the laboratory's procedures for achieving traceability of measurements;

_____ (viii) the laboratory's scope of calibrations and/or tests;

_____ (ix) written procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

_____ (x) reference to the calibration, verification and/or test procedures used;

_____ (xi) procedures for handling calibration and test items;

_____ (xii) reference to the major equipment and reference measurement standards used;

_____ (xiii) reference to procedures for calibration, verification and maintenance of equipment;

_____ (xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes [see also (b)(2)(x), (c)(6)(ii), (g)(3)];

(xv) procedures to be followed for feedback and corrective action whenever:

_____ a) testing discrepancies are detected, or

_____ b) departures from documented policies and procedures occur;

_____ (xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;

_____ (xvii) procedures for dealing with complaints [see also (n)];

_____ (xviii) procedures for protecting confidentiality and proprietary rights [see also (b)(2)(ix)];

_____ (xix) procedures for audit and review;

_____ (xx) a description of the laboratory's policy regarding the use of the NVLAP logo;

_____ (xxi) a statement of the laboratory's policy for establishing and changing calibration intervals for equipment it controls; and

_____ (xxii) a statement of the laboratory's policy concerning the technique(s) to be used for determining measurement uncertainty and calibration/verification adequacy.

_____ (3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

_____ (4) The quality system adopted to satisfy the NVLAP requirements shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

_____ (5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

_____ (i) internal quality control plans, such as control charts and other available statistical techniques;

NOTE: Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

_____ (ii) participation in proficiency testing or other interlaboratory comparisons [see also (b)(2)(x), (c)(2)(xiv), (g)(3)];

_____ (iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

_____ (iv) replicate testings using the same or different methods;

_____ (v) retesting of retained items;

_____ (vi) correlation of results for different characteristics of an item.

(d) ***Personnel*** [see also (c)(2)(v)]

_____ (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

_____ (2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

_____ (3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) ***Accommodation (facilities) and environment*** [see also (i)(3)]

_____ (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

NOTE: Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

_____ (2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

NOTE: It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

_____ (3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

_____ (4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

_____ (5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

_____ (6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE: While it is the laboratory's responsibility to comply with relevant health and safety requirements, this is outside the scope of this assessment.

(f) ***Equipment and reference materials***

(1) The laboratory shall:

_____ (i) be furnished with all items of equipment (including hardware, software, and reference materials) required for the correct performance of calibrations and tests;

_____ (ii) in those cases where the laboratory needs to use equipment outside its permanent control, including rented, leased and client-owned equipment, ensure that the relevant NVLAP requirements are met.

_____ (2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

_____ (3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

_____ (4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

_____ (i) the name of the item of equipment, software or reference material;

_____ (ii) the manufacturer's name, type identification, and serial number or other unique identification;

_____ (iii) date received and date placed in service;

NOTE: For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

_____ (iv) current location, where appropriate;

_____ (v) condition when received (e.g., new, used, reconditioned);

_____ (vi) copy of the manufacturer's instructions, where available;

_____ (vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

_____ (viii) details of maintenance carried out to date and planned for the future;

_____ (ix) history of any damage, malfunction, modification or repair;

▸ _____ (x) measured value observed for each parameter found to be out of tolerance
▸ during calibration/verification.

(g) ***Measurement traceability and calibration***

_____ (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

_____ (2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever applicable, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

NOTE: Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement.* Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

NOTE: A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.

_____ (3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing [see also (b)(2)(x), (c)(2)(xiv), (c)(6)(ii)].

NOTE: Traceability requirements may also be satisfied by:

(i) internationally accepted standards in the field concerned;

(ii) suitable reference materials;

(iii) ratio or reciprocity measurements; or

(iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

_____ (4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

_____ (5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

_____ (6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

_____ (7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) ***Calibration and test methods***

_____ (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

_____ (2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

NOTES:

(i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

(ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

_____ (3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

_____ (4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports [see also (k)(2)(x)].

_____ (5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples [see also (k)(2)(ix)].

_____ (6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall have written procedures which ensure that:

_____ (i) the NVLAP requirements are complied with;

_____ (ii) computer software, computers or automated equipment is documented and adequate for use;

_____ (iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

_____ (iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data [see also (f)(1)];

_____ (v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

_____ (8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory [see also (m)(2)].

(i) ***Handling of calibration and test items***

_____ (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time [see also (k)(2)(v)].

_____ (2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

_____ (3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned [see also (e)].

_____ (4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

_____ (5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

NOTE: Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.

(j) ***Records***

_____ (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing [see also (c)(2)(iv)].

▸ **EXCEPTION:** The retention of all original observations, calculations, and
▸ derived data in the calibration record system is not a mandatory requirement
▸ for calibration laboratories, although it is encouraged as good laboratory
▸ practice.

_____ (2) All records (including those listed in (f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client [see also (b)(2)(ix), (c)(2)(xviii)].

NOTE: The period of retention shall be specified in the quality manual.

Record retention time specified: _____

(k) ***Certificates and reports***

_____ (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used [see also (k)(4)(i)].

NOTE: It is recognized that the results of each calibration do not always result in the production of a calibration certificate or report. Whenever a certificate or report is produced, the above requirements shall be met.

(2) Each certificate or report shall include at least the following information:

_____ (i) a title, e.g., "Calibration Certificate," "Test Report" or "Test Certificate";

_____ (ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

_____ (iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

_____ (iv) name and address of client, where appropriate;

_____ (v) description and unambiguous identification of the item calibrated or tested [see also (i)(1)];

_____ (vi) characterization and condition of the calibration or test item;

_____ (vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

EXCEPTION: Although it is encouraged as good laboratory practice, the requirement for inclusion of the date received is not mandatory for calibration laboratories.

_____ (viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

_____ (ix) reference to sampling procedure, where relevant [see also (h)(5)];

_____ (x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions [see also (c)(2)(xv), (h)(4)];

_____ (xi) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

_____ (xii) a statement of the estimated uncertainty of the calibration or test result, where relevant;

_____ (xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue [see also (c)(2)(vi)];

_____ (xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

_____ (xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

_____ (xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;

_____ (xvii) the signature of an approved signatory for all test and calibration reports endorsed with the NVLAP logo;

▸ _____ (xviii) special limitations of use; and

▸ _____ (xix) traceability statement.

_____ (3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified [see also (l)].

_____ (4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible [see also (k)(1)].

_____ (5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number ... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of item (j).

_____ (6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report, or test certificate or amendment to a report or certificate.

NOTE: Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

_____ (7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the NVLAP requirements are met and that confidentiality is preserved.

_____ (8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

_____ (i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and

_____ (ii) a clear indication of which data are not covered by the accreditation.

The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the accreditation, the client must be so advised.

(l) ***Subcontracting of calibration or testing*** [see also (k)(3)]

_____ (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

_____ (2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

_____ (3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:

_____ (i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;

_____ (ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s) and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;

_____ (iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;

_____ (iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and

_____ (v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

if NVLAP-accredited

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed"

if not NVLAP-accredited

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

(m) ***Outside support services and supplies***

_____ (1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

_____ (2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned [see also (h)(8)].

_____ (3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) ***Complaints*** [see also (c)(2)(xvii)]

_____ (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

_____ (2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the NVLAP requirements or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with item (c)(3).

(o) ***Measuring and test equipment (M & TE)***

NOTE: This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

(1) General requirements for M & TE

_____ (i) The supplier shall establish and document a system to control the calibration/verification of M & TE.

_____ (ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with sections 285.33(b) through (n).

_____ (iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

_____ (iv) All operations performed by the supplier in compliance with these requirements shall be subject to customer verification at unscheduled intervals.

_____ (v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with these requirements.

- Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

- Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

(2) Detailed requirements for M & TE

_____ (i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of section 285.33(o) and any deviations shall be submitted with supporting documentation to the customer for approval.

_____ (ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of items (f)(1), (g)(1), and (h)(2).

_____ (iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

_____ (iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

_____ (v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of items (h)(1) and (h)(2).

_____ (vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

_____ (vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with these requirements.

_____ (viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n).

_____ (ix) Records: These requirements shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

_____ (x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

_____ (xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to section 285.33 (l) to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.

_____ (xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

NVLAP LAB CODE: [ ]

GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

NVLAP LAB CODE: [ ]

GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

APPENDIX C

SPECIFIC OPERATIONS CHECKLIST

NVLAP LAB CODE: _____

BULK ASBESTOS SPECIFIC OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses specific accreditation criteria prescribed in applicable sections of Handbook 150-3.

Place an "X" beside any of the checklist items which represent a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments on this list or on the comment sheet(s). Place a check beside all other items you observed or verified at the laboratory.

1 Organization and management

See General Operations Checklist

2 Quality system, audit and review

_____ 2.1 The laboratory shall ensure that the quality assurance analyses represent at least 10% of the total number of analyses performed.

_____ 2.2 The laboratory shall maintain and summarize all of the quality assurance activities each month to include:

- _____ contamination checks using asbestos-free material, such as the glass fiber blank in SRM 1866;
- _____ internal and NIST proficiency testing for each analyst;
- _____ interlaboratory analyses;
- _____ overall accuracy and precision for each microscopist for qualitative and quantitative analyses as defined in its quality documentation;
- _____ identification of any sample custody errors, such as mixing up samples, losing samples, etc.;
- _____ comparison of results of independent techniques with PLM results, if appropriate;
- _____ deficiency corrections;
- _____ an estimate of the total failure rate of the laboratory based on combination of all errors above.

_____ 2.3 The laboratory shall have the following documents available:

_____ NIST Handbook 150;
_____ U.S. Environmental Protection Agency's "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Subpart F, Appendix A, or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building materials;
_____ AHERA - 40 CFR Part 763, Vol. 52, No. 210: "Asbestos Containing Materials in Schools; Final Rule and Notice";
_____ reference text(s) on optical mineralogy and crystallography;
_____ general reference text(s) on statistics and quality assurance;
_____ U. S. Environmental Protection Agency's "Method for the Determination of Asbestos in Bulk Building Materials" (EPA/600/R-93/116), July 1993, R.L. Perkins and B.W. Harvey.

_____ 2.4 The laboratory's quality documentation contains procedures or instructions describing the following:

_____ training of staff and quality assurance of analyst performance;
_____ sample custody and handling procedures;
_____ analysis of samples and methods to ensure the accuracy and precision of analyses;
_____ equipment maintenance and calibration of refractive index liquids;
_____ contamination control;
_____ record keeping and generation of reports.

_____ 2.5 The laboratory shall have a description of its staff training program including its criteria for successful completion. The training program shall include training with blanks and blind testing to determine competency. New analysts' results shall be checked by either an experienced analyst (with an acceptable error rate) or by an independent technique until the analyst has an acceptable error rate. Analysts and technical supervisors shall participate in some form of continuing education, such as formal course work, in-house education, and scientific or technical meetings, and have access to journals that describe advances in the field of microscopy and/or asbestos analysis.

_____ 2.6 The laboratory shall conduct an internal audit of the laboratory not less than annually to verify that the operations of the laboratory are in compliance with its quality manual and this program.

3 Personnel

_____ 3.1 The laboratory shall ensure that staff members are aware of the extent of their area of responsibility.

_____ 3.2 The laboratory shall ensure that:

_____ analyst(s) have an understanding of and can measure the index of refraction by the immersion method;

_____ analyst(s) understand polarized light microscopy sufficiently to conduct analyses. They understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component. (e.g., an analyst using focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index);

_____ analyst(s) are competent with the polarized light microscope. They can properly align the microscope and identify all the crucial parts;

_____ analyst workload is consistent with accurate and precise analytical measurement;

_____ technical supervisor(s) shall have a fundamental knowledge of the method to assure the quality of the laboratory's results.

_____ 3.3 The laboratory shall maintain documentation for each staff member which contains:

_____ staff member's title and description of that job position;

_____ job and quality assurance responsibilities;

_____ résumé;

_____ training;

_____ assigned laboratory procedures and duties;

_____ results of quality assurance activities including precision and accuracy, and the results of NVLAP proficiency testing;

_____ accuracy, precision and error data;

_____ correction of deficiencies.

4 Accommodation (facilities) and environment

_____ 4.1 The laboratory has the proper facilities, including space, lighting, environmental control, etc. to perform analyses and store asbestos adequately.

_____ 4.2 The laboratory uses blanks of asbestos-free material to determine the presence, quantity, and consistency of asbestos contamination in their analytical process and has related procedures to control it.

5 Equipment and reference materials

_____ 5.1 The laboratory shall have the following equipment and materials:

- _____ biohazard hood of Class I or with a HEPA filter;
- _____ sampling utensils, (scalpels, forceps, probes, needles, tweezers, razors, etc.);
- _____ microscope slides and cover slips;
- _____ refractive index liquids, 1.490-1.570 and 1.590-1.720 in increments of less than or equal to 0.005 (high dispersion liquids are optional);
- _____ stereomicroscope or low power binocular microscope, approximately 10-45X, with light source;
- _____ mortar and pestle;
- _____ sample containers (ceramic bowls, glass plates, petri dishes, glassine paper, etc.);
- _____ thermometer.

_____ 5.2 The laboratory shall have a polarized light microscope (PLM) with:

- _____ binocular or monocular with cross hair reticle (or functional equivalent);
- _____ low ($\geq$5X and $\leq$15X), medium ($>$15X and $<$40X), and high ($\geq$40X) objectives;
- _____ light source;
- _____ 360-degree rotatable stage;
- _____ substage condenser with iris diaphragm;
- _____ polarizer and analyzer that can be placed at 90° to each other;
- _____ accessory slot at 45° to polarizers for wave plates and compensators;
- _____ wave retardation plate ($\sim$ 550 nm retardation);
- _____ dispersion staining objective complete with accessories (optional);
- _____ test slide (or a standard such as SRM 1866) for aligning the cross hairs with the privileged directions of the polarizer and analyzer.

_____ 5.3 The laboratory shall ensure that each microscope is in proper working condition. The optical system, including objectives, condensers, polarizers, etc., are not damaged or modified in any way that would affect microscope resolution or depolarize the light. (i.e., the lens is relatively free of scratches, nicks, corrosion, signs of impact, etc., and there is no stop in the back focal plane other than for dispersion staining objectives).

_____ 5.4 The laboratory shall align the polarized light microscope daily (or prior to use) in such a way that:

- _____ the substage polarizer and the analyzer are oriented at 90 degrees to one another. The orientations of the privileged directions of the polarizers must be known. The accessory slot must be at 45 degrees to these privileged directions;
- _____ the ocular cross hairs coincide with the privileged directions of the polarizer and the analyzer and this condition is verified with a test slide (or similar standard);
- _____ the objectives and/or stage are centered to prevent any grains from leaving the field of view during stage rotation;
- _____ the condenser and iris diaphragm are centered on the optic axis.

_____ 5.5 The laboratory has reference materials for chrysotile, amosite, crocidolite, tremolite, actinolite, anthophyllite and glass fiber traceable to NIST (SRM 1866 and SRM 1867).

Note: These SRMs are available from the NIST Standard Reference Materials Program (SRMP), Room 204, Building 202, NIST, Gaithersburg, MD 20899, 301-975-6776.

_____ 5.6 The laboratory has calibrated refractive index solids or refractometer (or access to) for calibrating refractive index liquids.

_____ 5.7 The laboratory shall have written procedures for calibrating refractive index liquids:

- _____ frequently enough to ensure reliable calibration;
- _____ within an accuracy of ±0.004;
- _____ including room temperature measurement of ±2 °C.

_____ 5.8 The laboratory maintains the necessary equipment for any optional procedure(s) it performs.

6 Measurement traceability and calibration

_____ 6.1 The laboratory shall have an error rate of less than 1% on the qualitative analysis (asbestos present or not and type) of samples containing greater than trace amounts of chrysotile, amosite, or crocidolite.

_____ 6.2 The laboratory shall identify problem samples, such as floor tiles, that are difficult to analyze qualitatively and shall have specific procedures to deal with the problem samples to reduce the errors to less than 1%.

_____ 6.3 The laboratory shall have procedures describing how reference standards are used to verify the accuracy of an analyst's ability to correctly determine the optical properties of asbestos.

_____ 6.4 The laboratory determines precision on the qualitative and quantitative analyses of samples by:

- _____ repeat analyses by the same analyst;
- _____ comparison of results from multiple slide mounts of the same material;
- _____ analysis of samples by multiple analysts if possible (single analyses laboratories require more interlaboratory data);
- _____ analysis of samples by other laboratories.

_____ 6.5 The laboratory determines the accuracy of the qualitative and quantitative analyses of samples by:

- _____ analysis of proficiency testing materials;
- _____ analysis of standards either prepared in-house or purchased;
- _____ analysis of samples using independent methods (XRD, gravimetry, etc).

_____ 6.6 The laboratory uses blanks of asbestos free material to test for contamination.

_____ 6.7 The laboratory keeps control charts showing the results of precision and accuracy tests.

_____ 6.8 If an estimation technique that is equivalent to point counting is used, the laboratory:

_____ 6.8.1 uses one or more of the following for calibration:

_____ bulk standards;
_____ prepared (permanent) slides that have been point-counted;
_____ photomicrographs of grain mounts that have been calibrated for relative area;
_____ other appropriate standards;

_____ 6.8.2 has data to show equivalency to point counting.

7 Test methods and calibration

_____ 7.1 The laboratory uses the U.S. Environmental Protection Agency's "Interim Method for the Determination of Asbestos in Bulk Insulation Samples" as found in 40 CFR, Part 763, Subpart F, Appendix A, or the current U.S. Environmental Protection Agency method for the analysis of asbestos in building materials.

_____ 7.2 The laboratory shall have a clear definition of each asbestos type that includes the acceptable optical properties (e.g., such as the range in refractive indices), that the fibers can exhibit and still be identified as the particular asbestos type, and what constitutes asbestiform morphology.

_____ 7.3 The laboratory shall determine the identification of fibrous materials by the measuring the following optical properties:

_____ morphology;
_____ color and pleochroism;
_____ indices of refraction (n_D) parallel and perpendicular for chrysotile, amosite, crocidolite; γ and α for anthophyllite, actinolite, and tremolite if they display biaxial optics;
_____ birefringence;
_____ extinction characteristics;
_____ sign of elongation.

_____ 7.4 The laboratory shall have a written procedure for dealing with samples in which the fibers are heavily coated with binder that hinders analysis.

_____ 7.5 The laboratory must maintain a list of non-asbestos fibers that can be confused with asbestos and the specific optical properties for each that can be used to distinguish between asbestos and non-asbestos.

_____ 7.6 The laboratory shall measure and record at least one optical property for non-asbestos fibers that serves to distinguish them from asbestos.

_____ 7.7 The laboratory shall have specific sample preparation techniques for dealing with samples that are semi- or non-friable.

_____ 7.8 The laboratory shall use the point-count technique or a technique that it has demonstrated and documented to be equivalent for quantitative analysis.

_____ 7.9 The laboratory shall homogenize the sample in some way or analyze a sufficient number of subsamples to obtain a representative analysis.

_____ 7.10 The laboratory shall have a working definition of trace and be able to distinguish between trace concentrations of asbestos and concentrations near 1%.

8 Handling of calibration and test items

_____ 8.1 The laboratory shall have a sample log system used to uniquely identify the test item and document the action. The log shall include:

- _____ date of receipt of the test item;
- _____ the condition of the test item;
- _____ documentation of acceptance or rejection of test item, reasons for rejection (e.g., air samples mixed with the bulk samples);
- _____ a unique laboratory identification number for each test sample;
- _____ the client identification number, which is the number that the client (or sample taker) assigns to the test item;
- _____ the initials of the person making the above entries in the sample log book.

_____ 8.2 Where there is any doubt as to the test item's suitability for testing (e.g. too small of a sample size, a mismatch between identification and description, or whether they are of a type which can be analyzed by the laboratory), the laboratory shall have a procedure for informing the client and resolving the problem. This action shall be documented.

_____ 8.3 The laboratory shall:

- _____ have written procedures to ensure that bulk samples are stored safely and securely;
- _____ dispose of bulk samples in a safe manner and in accordance with any and all federal, state and local regulations;
- _____ document the disposal/return of bulk samples and retain the documentation with all other data and information regarding the sample;
- _____ properly store materials to prevent damage or cross contamination;
- _____ hold samples for a minimum of 30 days after analysis unless earlier return is requested by the client or prevented by law or regulation.

9 Records

_____ 9.1 The laboratory shall have a description of the laboratory's record-keeping system.

_____ 9.2 The laboratory shall have documentation, either electronic backup or "paper" hard copy, to verify survival of original data if computers are used for data retention.

_____ 9.3 The laboratory maintains in its records all the required optical data for each analysis that it performs.

_____ 9.3.1 The laboratory records the following stereomicroscopical data for bulk examination to include:

- _____ homogeneity;
- _____ texture;
- _____ color;
- _____ estimated concentration of asbestos.

_____ 9.3.2 The laboratory records the following data for the asbestos type(s) by PLM examination:

- _____ morphology;
- _____ color and pleochroism;
- _____ indices of refraction (n_D) parallel and perpendicular for chrysotile, amosite, crocidolite; γ and α for anthophyllite, actinolite, and tremolite if they display biaxial optics;
- _____ birefringence;
- _____ extinction characteristics;
- _____ sign of elongation;
- _____ estimated concentration of asbestos;
- _____ result of analysis.

_____ 9.4 The laboratory shall ensure that the analyst signs (or initials) and dates the original data.

_____ 9.5 The following records are maintained for a minimum of 3 years:

- _____ sample custody;
- _____ original data collected by analyst;
- _____ contamination monitoring data;
- _____ calibration and verification data;
- _____ quality control activities and results;
- _____ equipment and maintenance;
- _____ test reports.

10 Certificates and reports

_____ 10.1 Each report shall include the following information:

- _____ color (and any other information that serves to macroscopically identify and describe the sample);
- _____ presence or absence of asbestos;
- _____ type or types of asbestos present;
- _____ estimate of the area percent for each type of asbestos present;
- _____ identity of other fibrous materials (if known);
- _____ estimate of the area percent for other fibrous materials present (if known);
- _____ identity of matrix materials if known;
- _____ a statement is made if the sample is inhomogeneous and if subsamples of the components were analyzed separately;
- _____ a description of any problems encountered in the analysis;
- _____ departures from the test method;
- _____ an approved signatory's signature.

_____ 10.2 The laboratory shall report the results of samples containing one or more layers consistent with the most current guidelines.

_____ 10.3 The laboratory shall ensure that the client receives a "hard copy original" of the test report by mail, notwithstanding initial transmittal by facsimile, telex or other electronic means.

11 Subcontracting of calibration or testing

See General Operations Checklist

12 Outside support services and supplies

See General Operations Checklist

13 Complaints

See General Operations Checklist

14 Proficiency testing

_____ The laboratory shall participate in the mandatory NVLAP Proficiency Testing program, which includes (but is not limited to) the following:

- _____ analyses are not contracted out to another laboratory;
- _____ laboratory keeps and utilizes proficiency testing materials for use as in-house instructional materials;
- _____ all analysts (full and part time) participate in all proficiency testing rounds (all analysts need not participate in proficiency testing prior to returning the results to NVLAP, but all analysts shall participate without prior knowledge of the testing results at a later date);
- _____ each analyst separately analyzes, records and reports test results;
- _____ one single result is reported back to NVLAP by the laboratory unless otherwise specified in the testing instructions;
- _____ procedures and calculations (if any) are documented as to how the one single result was determined;
- _____ problems indicated by proficiency testing are discussed with appropriate laboratory personnel and documented;
- _____ plans are developed and implemented for resolving problems and are documented;
- _____ the test results are used in determining accuracy and precision for each analyst.

15 Sub-facilities

_____ 15.1 The sub-facility **is technically dependent** on the main facility (i.e., technical management and supervision are provided by the main facility.

_____ 15.2 Quality assurance activities of the sub-facility are directed by the main facility.

_____ 15.3 The nature, scope, and frequency of on-site quality assurance reviews, by the main facility quality manager (or equivalent), are:

- _____ clearly defined in the quality manual;
- _____ appropriate for the nature and scope of work performed by the sub-facility.

_____ 15.4 All permanent quality assurance and personnel records are retained at the main facility.

_____ 15.5 Quality assurance data from each sub-facility are regularly and routinely compared both to the main facility's data and data from other sub-facilities. Records of such comparisons are retained in quality assurance records along with actions taken to evaluate and resolve differences.

_____ 15.6 Analysts at sub-facilities participate in NVLAP proficiency testing and records are maintained of individual results.

NVLAP LAB CODE: [ ]

SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

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